EXPLANATORY MEMORANDUM TO

The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2010

2010 No. 321

1. Introduction

1.1 This explanatory memorandum has been prepared by the Food Standards Agency Northern Ireland to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2 The Statutory Rule is made under Articles 15(2), 16(1) and (2), 25(1)(a), 2(a) and (3),32 and 47(2) of the Food Safety (Northern Ireland) Order 1991 as read with paragraph 1A of Schedule 2 to the European Communities Act 1972.

2. Purpose of the Rule

2.1 This rule provides for the enforcement in Northern Ireland of the remaining provisions of Commission Regulation (EC) No. 450/2009 ("the AIM Regulation"), on active and intelligent materials and articles intended to come into contact with food. It will designate district councils as having responsibility for the enforcement of the AIM Regulation in Northern Ireland.

2.2 This rule provides for offences of contravening certain provisions of the AIM Regulation and for defences against prosecution for committing an offence in particular circumstances and specifies the penalties that the Courts may impose upon conviction for an offence.

2.3 This rule will also revoke the Materials and Articles in Contact with Food Regulations (Northern Ireland) 2007[1] and the Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2009[2]

3. Matters of special interest to the Health Committee

3.1 None

4. Legislative Context

4.1 The general principles on all food contact materials and articles intended to come into contact with foodstuffs are established in Regulation (EC) No. 1935/2004[3]. This lays down the framework of regulation for all materials and articles intended to come into contact with food, including those classed as 'active; and 'intelligent'. The AIM Regulation is a specific measure within the meaning of Article 5(1)(b) of the framework Regulation. This establishes specific rules for active and intelligent materials and articles to be applied in addition to the general requirements established in the framework Regulation for their safe use. The enforcement of provisions for that Regulation are implemented in Northern Ireland by The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2007. This rule will revoke the 2007 and 2009 Regulations and remake them with necessary amendments taking into account the remaining enforcement provisions of the AIM Regulation.

[1] SR 2007 No. 434
[2] SR 2009 No. 377
[3] OJ L338, 13.11.2004

4.2 The AIM Regulation puts in place safety requirements that have to be met by businesses seeking to place on the market active and intelligent food packaging systems that extend the normal shelf life or maintain, or improve the condition of, packaged food and are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food. The labelling and declaration provisions provide businesses and consumers with better information regarding packaged food and prevent businesses misleading consumers about the product they are buying. The AIM Regulation also lays down the procedure that manufacturers of such packaging systems must follow to have their product authorised at European Union (EU) level and dates by which goods must comply with the requirements and when goods will be in breach of them.

4.3 The AIM Regulation also requires that only substances in the Community list of authorised substances may be used in components of active and intelligent materials and articles. In order for substances to be included in the Community list, specific conditions must be met and these have to satisfy the requirements of Article 3 and, where they apply, Article 4 of the framework Regulation for their intended use. The Community list will be established in agreement with the Member States, with detail on the deadlines by which events pertaining to the list must be completed and procedures for drawing up the list. The list will be drawn up in accordance with the applications made under Article 9 of the framework Regulation and adopted by the Commission under the procedure set out in Articles 10 and 11 of the that Regulation.

4.4 Applications for the inclusion of substances in the Community list must be submitted within 18 months of the publication of the European Food Safety Authority (EFSA) Guidelines for safety assessment of substances – that is to say by 31st May 2011. The EFSA Guidelines were issued on 30th November 2009[4].

5. Territorial Extent and Application

5.1 This rule applies to Northern Ireland.

5.2 Separate but parallel legislation is being drawn up in England, Scotland and Wales.

6. European Convention on Human Rights

6.1 As the Rule is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- What is being done and why

7.1 The EU legislation aims to protect the nature and quality of the food concerned and to provide clear and consistent conditions for the trade in goods. The purpose of making this rule ensures that the provisions outlined above provide the necessary powers to enforcement authorities for the effective enforcement of the AIM Regulation and to fulfil their statutory obligations. It is also our aim to simplify the way rules governing these articles and materials are presented in Northern Ireland to make them as plain as possible to those that need to refer to them. This decision has been taken with industry support.

[4] http://ec.europe.eu/food/food/chemicalsafety/foodcontact/documents_en.htm

7.2 It is the intention that the law on materials and articles intended to be brought into contact with food should protect human health from adverse effects and from any chronic health effect over a person's lifetime arising from the consumption of food that could be contaminated with chemicals used in the manufacture of materials and articles. The intention is particularly to protect consumers from substances that might be carcinogenic, mutagenic or toxic to reproduction. It also aims to the nature and quality of the food concerned and to provide the industry with one set of harmonised rules that apply throughout the EU, instead of a plethora of different national rules in each of the twenty seven EU Member States.

- ***Consolidation***

7.3 The policy of maintaining a simplified set of Regulations is being continued. For this reason, rather than implementing the enforcement provisions by further amending the 2007 Regulations mentioned in paragraph 4.1, those Regulations will be revoked and re-made, with necessary amendments in a consolidated rule that includes the remaining enforcement provisions of the AIM Regulation. This will ensure that we continue to keep to a minimum the number of rules to which stakeholders such as business operators and enforcement authorities need to refer.

8. Consultation outcome

8.1 The Food Standards Agency in Northern Ireland undertook a 12-week public consultation in order to gather stakeholder views on the draft regulations. One response was received in Northern Ireland, which was supportive of the proposed Regulations.

9. Guidance

9.1 Guidance for business has been developed and formed part of the stakeholder consultation on the proposed Regulations. The Guidance has been finalised and sent to stakeholders and has also been published on the Agency's website at: http://www.food.gov.uk/foodindustry/guidancenotes/foodguid/plasticsguidance

10. Equality Impact

10.1 These regulations will apply in equal measure to all Section 75 groups. It is not expected that any of these changes will impact differently across any of the Section 75 groups.

11. Impact

11.1 Any impact on businesses from these regulatory proposals is likely to be for familiarisation costs associated with the proposed Regulations. These include the reading and dissemination of the Regulations to key staff within the organisation. The primary business sector that will be affected by the regulatory proposals will be manufacturers, importers, converters and fillers of food contact materials and more specifically those using active and intelligent components in their packaging. These proposals have no particular impact on, charities or voluntary bodies; rural areas nor on members of the ethnic communities of any particular racial group.

11.2 The Agency has sponsored two pieces of research on active and intelligent packaging; the first was published in 2004 and the second in 2009. The first found that the then UK market for active and intelligent packaging was small and concluded that the major impact of any wider introduction of such packaging would fall on sectors of direct food additives, food authenticity and food labelling. Its other findings concerned the nature of legislation

on such materials and articles much of which has now been enacted in the AIM Regulation.

11.3 The second sought, among other things to explore the market for these materials and articles. Once again, only a small, unquantified number of companies were found marketing active and intelligent materials in the UK, so the search was extended and over 60 companies worldwide were identified. The products found included; oxygen scavengers, moisture absorbers, gas scavengers, carbon dioxide regulators, antimicrobial releasing systems, nitrogen, heat and flavour releasers and monitoring systems.

11.4 Although the impact on the public sector is negligible, there may be an impact on the Food Standards Agency as and when it carries out surveys on foods. This impact may involve having to carry out more research into the migration of substances from food contact materials, including work to establish methodologies for determining such migration and to ensure compliance with the legislation.

11.5 The Agency may also be affected via its enforcement role with regard to the framework Regulation in respect of declarations of compliance, as indicated in Article 16 of that Regulation. Article 12 and Article 13 of the AIM Regulation requires that appropriate documentation be made available to competent authorities on demand to show that their products comply with the legislation.

11.6 An Impact Assessment is attached to this memorandum. This IA has been prepared by FSA colleagues in England but it is believed to be equally representative of the situation in Northern Ireland.

12. Regulating Small Business

12.1 The legislation on food contact materials and articles will apply to all businesses small and large.

12.2 The impact on small and medium sized businesses is unlikely to be significant. This view has been supported by industry following earlier consultations, when they indicated that the proposals would not disproportionately affect them, nor would they hinder competitiveness. Such businesses are also encouraged to respond to issues which they feel may have an impact on their ability to compete in the wider market. To date no comments have been received from small businesses.

13. Monitoring and Review

13.1 The Agency will work with enforcement authorities where problems arise or suspected infringements of the Regulations arise. The effectiveness of the Regulations will be also be monitored via feedback from stakeholders as part of the ongoing policy process and will be reviewed in March 2011.

14. Contact

Mervyn Briggs at the Food Standards Agency NI, Tel: 028 9041 7742,

Email: mervyn.briggs@foodstandards.gsi.gov.uk

Title:	Impact Assessment (IA)
The Materials and Articles in Contact with Food (England) Regulations 2010 **Lead department or agency:** Food Standards Agency **Other departments or agencies:**	**IA No: FOODSA0022** **Date: 1st August 2010** **Stage: Final** **Source of intervention: EU** **Type of measure:** Secondary Legislation **Contact for enquiries:** Nasreen Shah Tel: 020 7276 8553

Summary: Intervention and Options

What is the problem under consideration? Why is government intervention necessary?

Chemical migration from food contact materials can detrimentally affect consumer health. Most consumers are unable to assess the risk involved when consuming a product because of the lack of knowledge of the chemical migration and production methods and therefore cannot make informed choices about such risk. Government intervention is necessary to minimise risk to health and also to provide greater clarity in enforcement.

What are the policy objectives and the intended effects?

To minimise the long term risks to consumers in England from ingesting chemicals used in the manufacture of active and intelligent materials and articles that can accidentally migrate into food, by making enforcement provisions that enable the food authorities to ensure that products placed on the market are safe, and thus increase consumer confidence.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

1. Do Nothing. This will not prevent the Commission Regulation from being in force in England; it is already legally binding and applicable throughout the European Union (EU). However, enforcement authorities would not have the necessary powers to enable them to enforce it.

2. Option 2. Make appropriate domestic Regulations for the proper enforcement of the Commission Regulation and provide for offences for not complying with the EC Regulation. This ensures that the enforcement authorities have the necessary powers that will enable them to fulfil their responsibilities under the Food Safety Act 1990, as amended.

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	It will be reviewed October 2011
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	No

Ministerial Sign-off For enactment stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister:..... Date:.....

Summary: Analysis and Evidence Policy Option 2

Description:

Fully implement the necessary requirements that will support the European Regulation and provide for its enforcement

Price Base Year 2009	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£)		
			Low:	High:	Best Estimate:-120,000

COSTS (£)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A		N/A	**N/A**
High	N/A		N/A	**N/A**
Best Estimate	120,000		N/A	**N/A**

Description and scale of key monetised costs by 'main affected groups'

Familiarisation costs £120,000 which is split £14,700 familiarisation cost for Local Authorities, £2,600 familiarisation cost to Port Health Authorities and £102,800 familiarisation cost to industry.

Over a 10 year period the total equivalent annual cost in England is approximately £14,431

Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A		N/A	**N/A**
High	N/A		N/A	**N/A**
Best Estimate	N/A		N/A	**N/A**

Description and scale of key monetised benefits by 'main affected groups'

No benefits monetised. See non-monetised benefits below.

Other key non-monetised benefits by 'main affected groups'

Minimise the potential for consumers to be exposed to harmful levels of substances that could pose a risk to human health. Increased protection of public health and the preservation of exports to other Member States. Greater clarity for business and enforcement officials through formalisation of existing procedures and maintenance of consumer confidence.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

The goods that are subject to the Commission Regulation that the England Regulations give full effect to are innovative products. Ensuring safety restrictions on their use are properly enforced by authorities in England will develop trust among consumers that these new products are safe and will increase consumer confidence in them.

Impact on admin burden (AB) (£m):	Impact on policy cost savings (£m):	In scope

New AB:	AB savings:	Net:	Policy cost savings:	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			October 2010		
Which organisation(s) will enforce the policy?			LA's and PHA's		
What is the annual change in enforcement cost (£m)?			N/A		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:**	**Benefits:**	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro** N/A	**< 20** N/A	**Small** N/A	**Medium** N/A	**Large** N/A
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[5] Statutory Equality Duties Impact Test guidance	Yes	17
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	17
Small firms Small Firms Impact Test guidance	No	17
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	throughout
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainable development Sustainable Development Impact Test guidance	Yes	17

[5] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

References

No.	Legislation or publication
1	2006 Consultation http://www.food.gov.uk/consultations/consulteng/2006/?completed=Yes
2	2008 Consultation http://www.food.gov.uk/consultations/consulteng/2008/?completed=Yes
3	2009 Consultation (specific labelling and documentation provisions) http://www.food.gov.uk/consultations/consulteng/2009/materialarticlefoodengregs09
4	EU Legislation http://eur-lex.europe.eu/LexUriServ.do?uri=OJ:L2009:135:0003:0011:EN:PDF
5	2009 Statutory Instrument http://www.opsi.gov.uk/si/si2009/uksi_20092938_en_1
6	2010 Consultation on draft Statutory Instrument http://www.food.gov.uk/consultations/consulteng/2010/materialsarticlesfoodregs2010eng

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Evidence Base

Annual profile of monetised costs and benefits* - (£) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs	14,131	14,131	14,131	14,131	14,131	14,131	14,131	14,131	14,131	14,131
Annual recurring cost	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total annual costs	14,131	14,131	14,131	14,131	14,131	14,131	14,131	14,131	14,131	14,131
Transition benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Annual recurring benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total annual benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

*** For non-monetised benefits please see summary pages and main evidence base section**

Evidence Base (for summary sheets)

Policy objective

To continue to reduce the long term health risks to consumers in England arising from chemical migration from materials and articles intended to come into contact with food.

1. The UK's aim is to minimise the long term health risks to consumers in England arising from ingesting chemicals used in the manufacture of materials and articles that may adventitiously migrate into food. This risk can be minimised by providing harmonised rules within which business can compete and to provide EU harmonised regulations that provide businesses with clear provisions that lead to safe products and increase consumer confidence.

Rationale for Intervention

2. Point to note[6] Chemical migration from food contact materials and articles can create a negative cost to others through detrimentally affecting consumer health. Most consumers are unable to assess the risks involved when consuming a product because they cannot observe the level of chemical migration and do not have full information on the production methods. Therefore, they cannot make informed choices about such risk. Government intervention is necessary to minimise these impacts on health, to ensure consumers can make informed choices and also provide greater clarity for the enforcement of the Commission Regulation.

3. These proposals fulfil the Government's policies of meeting its European Union (EU) obligations to bring into effect in law harmonised rules that:

- Reduce chronic and acute health risks to consumers arising from chemical contaminants in the food they eat; and
- Meet the intergovernmental Lisbon Agenda aimed at improving the competitiveness of businesses in Europe by providing harmonised rules that are not overly burdensome within which businesses can compete on an equal footing.

4. The Food Standards Agency ("the Agency") believes that the adoption of these proposals provides essential powers to enforce the modernised regulatory framework that removes trade barriers and allows technological innovation. Consumer protection will be enhanced in an area of food control where inadequate controls could have serious long-term implications or are suspected of carrying an unacceptable risk to consumer health, particularly among vulnerable people. The introduction of harmonised and detailed statutory controls also minimise the potential for uncertainty or dispute in interpreting what constitutes safe levels of extraneous substances in foods.

Intended effect

5. The EU legislation aims to protect the nature and quality of the food concerned and provides for the consistent and clear conditions for the trade in goods. The provisions proposed here for England aim to provide the enforcement authorities with the necessary powers and means to fulfil their statutory obligations. It is also our aim to simplify the way rules governing these articles and materials are presented in England to make them as plain as possible to those that need to refer to them. This decision was taken with industry support.

6. This proposal is for a Statutory Instrument (SI) entitled The Materials and Articles in Contact with Food (England) Regulations 2010. The objective of the proposed Regulations is to implement the remaining enforcement provisions for Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with foods ("the AIM Regulation), by:

- designating local authorities and port health authorities as having responsibility for the enforcement of the AIM Regulation in England;
- providing for offences of contravening certain provisions of the AIM Regulation and for defences against prosecution for committing an offence in particular circumstances; and
- specifying the penalties that the Courts may impose upon conviction for an offence.

[6] Since the Lisbon Treaty came into force, all references to "Community" are deemed to be references to the EU. However, in the narrative that follows we have used the terms in the legislation.

7. The proposed Regulations will also revoke *The Materials and Articles in Contact with Food (England) Regulations 2007* as amended by the Materials and Articles in Contact with Food (England) (Amendment) Regulations 2009 ("the 2009 Regulations"), and re-enact them with necessary amendments, thus implementing in one consolidated instrument the AIM Regulation as well as other controls on materials and articles in contact with food. The proposed Regulations will provide for the effective enforcement of the remaining provisions of the AIM Regulation, which are discussed below.

Background

8. The general principles governing the safety of all materials and articles intended to come into contact with foodstuffs are established in Regulation (EC) No. 1935/2004[7] ("the framework Regulation"). This lays down the framework of regulation of all such materials and articles, including those classed as 'active' and 'intelligent'. The AIM Regulation is a specific measure within the meaning of Article 5(1)(b) of the framework Regulation. This establishes the specific rules for active and intelligent materials and articles to be applied in addition to the general requirements established in the framework Regulation for their safe use.

9. The AIM Regulation was published in the Official Journal (OJ) of the EU on 30th May 2009[8] and came into force on 18th June 2009 and is directly applicable throughout the EU. The AIM Regulation is also available and can be downloaded freely from the following website:

http://eur-lex.europe.eu/LexUriServ.do?uri=OJ:L2009:135:0003:0011:EN:PDF

10. In September 2009 a short four week consultation was held to put in place a number of enforcement of provisions of the AIM Regulation that had to be place by 19th December 2009. These provisions related to particular labelling and declaration requirements for goods placed on the market. The December date refers to provisions at Article 4(f), 11(e) and 2 in the AIM Regulation. Article 14 of that Regulation required that these provisions be in place by that date. They specifically concerned the labelling of parts of the packaging that could be wrongly taken by some consumers to be edible, such as for example, a sachet containing a desiccant to prevent the food spoiling, being mistaken for condiment to use on the food; the written declaration of legal compliance to accompany active and intelligent materials and articles prior to retail sale; and the production, to enforcement authorities on request of supporting documentation to substantiate the declaration of compliance.

11. The enforcement provisions mentioned here were implemented in England by the 2009 Regulations[9]

Detail – Conditions for active and intelligent materials and articles

12. As explained in paragraph 8 above, the AIM Regulation is a specific measure within the meaning of Article 5(1)(b) of the framework Regulation. Many of its requirements reiterate and tie in with the overarching provisions of the framework Regulation and these are currently dealt with by the existing statutory instruments for England. The AIM Regulation lays down conditions that have to be met for these materials and articles to be placed on the market. That is to say that they must:

1. be suitable and effective for their intended purpose;
2. comply with the composition requirements set out in the AIM Regulation; and
3. be manufactured only from substances included in the 'Community list' of authorised substances, once that list has been adopted. However, this provision is followed by an exception that substances not included on the Community list may be used in components of active and intelligent materials and articles if they are:
    a) released active substances that comply with particular conditions;
    b) are substances falling within the scope of the Community or national provisions applicable to food, which are added to or incorporated into active materials and articles by techniques such as grafting or immobilisation in order to have a technological effect in the food, provided that they comply with the particular conditions set out;
    c) are substances used as components which are not in direct contact with food or the environment surrounding the food and are separated from the food by a functional barrier and comply with other conditions set out, and are not:

[7] OJ Ref L338, 13.11.2004
[8] OJ Ref L135, 30.05.2009 pg 3-11
[9] Statutory Instrument No. 2009/2938

i. substances classified as 'mutagenic', 'carcinogenic', or 'toxic to reproduction' in accordance with the criteria set out in sections 3.5, s.6 and 3.7 of Annex 1 to Regulation (EC) No. 1272/2008[10] of the European Parliament and the Council; or

ii. substances deliberately engineered to particle size which exhibit functional physical and chemical properties that significantly differ from those at a larger scale. In effect these are those substances commonly referred to as nano substances in England.

Conditions and content for inclusion of substances in the Community List

12.1 Substances may be included in the Community list where they satisfy the requirements of Article 3 and, where they apply, Article 4 of the framework Regulation for the intended conditions of use of the active or intelligent material or article. The information that will be contained in the Community list will specify:

a) the identity of the substance(s) and function of the substance(s)

b) the reference number and if necessary, the conditions of use of the substance(s) or component; and

c) if necessary, restrictions and/or specifications of use of the substance(s); and if necessary, conditions of use of the material or article to which the substance or component is added or into which it is incorporated.

Conditions of for the establishment of the Community list

12.2 These conditions include the means by which the Community list will be established, with detail on the deadlines by which preparatory stages pertaining to the list must be completed and the procedures for drawing up the list. The important deadlines are that the applications for the inclusion of substances in the Community list must be submitted within 18 months of the publication of the European Food Safety Authority's (EFSA) Guidelines for the safety assessment of substances. The Guidelines were issued on 31st November 2009, so the deadline for submission of applications is 31st May 2011. The initial Community list will be adopted by the Commission in agreement with Member States.

Conditions for use of substances not to be included in the Community list and transitional periods

12.3 Released active substances, and substances added or incorporated by techniques such as grafting or immobilisation shall be used in full compliance with the relevant Community or national provisions applicable to food (throughout these provisions the latter apply in the absence of the former), and shall comply with the provisions of the framework Regulation and, when applicable, its implementing measures. Additionally, the amount of released active substance shall not be included in the value of the measured overall migration, in cases where the overall migration limit (OML) is established in a specific Community measure for the food contact material in which the component is incorporated. The amount of a released active substance may exceed the specific restriction governing the food contact material it is contained in provided it complies with the Community or national provisions applicable to the food.

12.4 The migration into food of the substances behind a functional barrier shall not exceed 0.01 mg/kg, and the AIM Regulation refers to the conditions for measuring that migration. This limit shall always be expressed as a concentration in foods and it shall apply to a group of substances, if they are structurally and toxicologically related, (in particular, isomers or substances with the same relevant functional group), and it shall include possible set-off transfer.

12.5 As a transitional measure, where active and intelligent materials and articles are labelled in accordance with the framework Regulation and placed on the market prior to 19th December 2009, they shall be permitted to be sold until stocks are exhausted. Furthermore, that until the date of application of the Community list, released active substances shall be authorised and used in accordance with the relevant Community provisions applicable to food, and shall comply with the provisions of the framework Regulation and its implementing measures.

[10] On classification, labelling, packaging substances and mixtures, amending and repealing Directives 67/548/EEC and 19995/45/EC and amending Regulation (EC) No. 1907/2006

Supporting documentation

12.6 The AIM Regulation requires that appropriate documentation be made available to competent authorities on demand to show that products comply with the legislation. In order to demonstrate compliance, the supporting documentation must contain information on the suitability and effectiveness of the active or intelligent material or article, the conditions and detailed results of testing and or calculations and/or other analysis and evidence on the safety.

Options

Option 1 – Do nothing – This option would provide no enforcement of the AIM Regulation in England.

13. Doing nothing will not prevent the AIM Regulation from applying in England; it is already legally binding and applicable throughout the EU. However, enforcement authorities would not have the necessary powers to enable them to enforce it. Therefore, the obligation to put in place provisions for its enforcement, for offences to be prosecuted and for penalties for those found in breach of the AIM Regulation will not be fulfilled. This would lead the UK Government being cited in infraction proceedings by the Commission and these could result in financial penalties being incurred.

Option 2 – fully implement the necessary requirements and make appropriate domestic Regulations for the execution and enforcement that will support the AIM Regulation and provide for its enforcement.

14. This option would provide enforcement authorities with the necessary domestic legislation for the enforcement and execution of the AIM Regulation in England, which is binding in its entirety and directly applicable to all EU Member States.

Sectors and groups effected

15. Local authorities, port health authorities and industry will need to read and familiarise themselves with the new Regulations and take appropriate actions to achieve compliance. Charities and voluntary organisations are unaffected by these proposals.

Costs and benefits options

Benefits

Option 1 – Do nothing

16. There are no identifiable incremental benefits for option 1.

Option 2 – fully implement the necessary requirements and make appropriate domestic regulations for the execution and enforcement that will support the AIM Regulation and provide for its enforcement.

17. This option would ensure that enforcement authorities within England, including port health authorities, have adequate statutory powers to prevent the placing on the market of those materials and articles that fail to meet the requirements laid down in the AIM Regulation.

18. This option meets the Government's commitment to fulfil its EU obligations and contributes significantly to providing for the means of protecting consumers from ingesting harmful levels of chemicals that could have adventitiously migrated from the materials or articles that were intended to be brought into contact with the food. As a number of provisions of the AIM Regulation are already applicable and domestic enforcement measures in place, we are required to provide for the enforcement of the remaining provisions in England. This ensures that the enforcement authorities can fulfil the requirements placed upon them and the Courts can impose penalties that are consistent with those that apply elsewhere in English food law. It also provides for defences to alleged offences in certain specified circumstances.

19. Option 2 would also harmonise standards across Member States and prevent any barrier to trade occurring as a result of their being different regulations in different individual Member States. This option may even encourage additional trade and consolidate the important role that the UK plays in negotiating and agreeing standards for materials and articles intended to come into contact with food in within the EU.

20. Option 2 will also minimise the potential for consumers to be exposed to harmful levels of substances migrating from food contact materials and articles to the food itself. Whilst the potential benefits to health are difficult to quantify they are likely to include reduced risk of illness through exposure to substances that might migrate and might be associated with various effects on human health. In 1999 MAFF, now the Department of Environment, Food and Rural Affairs (DEFRA), published a report presenting economic evaluation of UK policy on chemical contaminants in food, which estimated that annual consumer benefit resulting from chemical contaminant controls was worth £900 million. The aim of the evaluation was to assess whether current controls on chemical contaminants and naturally occurring toxicants were cost effective and how these could be improved, taking into account the impact of such controls on consumers and the food supply chain. One of the report's conclusions was that the main beneficiaries were consumers, whilst the majority of the quantifiable costs had been borne by central government. The report is available on the DEFRA website at:

http://statistics.defra.gov.uk/esg/evaluation/chemcont/default.asp

Costs

Option 1

21. This option is the baseline for comparison.

Option 2

Costs to Enforcement Authorities

22. There will be a small one-off cost to businesses and enforcement authorities for reading and familiarising themselves with the new Regulations. The enforcement of food law is devolved to the enforcement authorities. In some case this is divided between the Environmental Health Departments of the local, district/borough etc councils and the Trading Standards Department of the county councils. In some instances these two departments of the different levels in local government liaise closely and deal with issues in common to make it easier for consumers and businesses.

23. Each Local Authority (LA) in its area and each Port Health Authority (PHA) in its district are responsible for enforcing the legislation with respect to food safety and/or food hygiene; and thus have responsibility for enforcing the food contact materials legislation and will, as outlined above be affected by these proposals. The Agency believes that the incremental costs to enforcement authorities are unlikely to have a significant cost impact and is likely to be minimal, if any. Local enforcement bodies have always had responsibility for the enforcement of food contact materials legislation. The proposed Regulations for England merely provide the means by which this role can be extended to cover the AIM Regulation.

24. There are a total of 354 LA's and 39 PHA's in England that will be affected by the proposed Regulations. It is expected that one Environmental Health Officer (EHO) from each LA and PHA will read the Regulations and disseminate information to key staff. For LA's we estimate that each EHO will invest one hour reading and familiarising themselves with the Regulations and a further hour disseminating to key staff in the organisation, meaning a total of two hours for familiarising. A consultation response from one PHA indicated that the hourly wage rate used does not appropriately reflect the actual wage. In order to maintain consistency across other impact assessments, we have continued to use the Office for National Statistics (ONS) Annual Survey of Hours and Earnings (ASHE) figure for the EHO hourly wage rate but have increased the amount of time used by PHAs to familiarise themselves with the Regulation from a total of two hours to three hours and 10 minutes. We have not amended the time taken to familiarise by LAs as no consultation responses were received on this. Earlier consultation responses have also indicated that the Trading Standards Officers (TSO's)[11] would need to read and understand these Regulations. We assume that the time taken would be the same as for EHO's.

25. A wage rate of £20.70[12] has been applied to each EHO which equates to a one-off familiarisation cost £14,653 for LA's and £2,574[13] to PHA's in England, which gives a total one-off familiarisation cost of £17,227.

[11] The Annual Survey of Hours and Earnings (2009) gives a median hourly pay, excluding overtime, for 'inspectors of factories, utilities and trading standards'.

[12] Wage rate obtained from the Annual Survey of Hours and Earnings (2009) (http://.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage rate of an 'Environmental health officer is used £15.92plus 30% overheads).

Equivalent Annual Costs (EAC)

26. In order 'one-off' transition costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalent annualise' costs using a standard formula[14]. Under Standard HMT Green book guidance[15] a discount rate of 3.5% is used.

27. Total one-off costs to enforcement authorities in England have been estimated as £17,227 (includes familiarisation costs of £14,653 Local Authorities and £2,574 for Port Health Authorities). This yields an EAC for industry in England of approximately £2,071 over 10 years and for the UK as a whole approximately £2,477[16]

Costs to Industry

28. Any likely costs to industry associated with the proposed Regulations relate only to the businesses such as manufacturers of active and intelligent packaging systems needing authorisation of the active components in their products and will not be incurred by the whole food packaging industry. The primary business sectors therefore likely to be affected by these proposals will be those that specifically manufacture and sell active and intelligent materials and articles intended to come into contact with food. For this sector, there will be a small one-off cost for reading and familiarising themselves with the new Regulations.

29. The Agency has sponsored two pieces of research on active and intelligent packaging. The first (A03039) was published in June 2004 and found that the then UK market for active and intelligent packaging was small. It is concluded from the research conducted, that the major impact of any wider introduction of such packaging would fall on sectors of direct food additives, food authenticity and food labelling. Its other findings concerned the nature of legislation on such materials and articles much of which has now been enacted in the AIM Regulation that these legislative proposals that are the subject of this Impact Assessment give full effect to.

30. The second, (A03062) was published in August 2009. It sought, among other things to explore the market for these materials and articles. Once again, only a small, unquantified number of companies were found marketing active and intelligent materials in the UK, so the search was extended and over 60 companies worldwide were identified. The products found included; oxygen scavengers, moisture absorbers, gas scavengers, carbon dioxide regulators, antimicrobial releasing systems, nitrogen, heat and flavour releasers and monitoring systems. A summary of both reports can be accessed at the following website addresses:

http://www.food.gov.uk/science/research/researchinfo/contaminantsresearch/contactmaterials/a03prog/a03projlist/a03039proj/

http://www.food.gov.uk/science/research/researchinfo/contaminantsresearch/contactmaterials/a03prog/a03projlist/a03062proj/

31. We have estimated that a manufacturer of active and intelligent packaging businesses will invest one hour reading and familiarising themselves with the new single set of Regulations. In addition, we have estimated that each person uses a further hour for dissemination to key staff within the organisation, meaning a total of two hours. There are 2,040 businesses in England which may manufacture and sell active and intelligent materials[17]. This is set out in table 2 below. A wage rate of £25.19[18] has been applied for a manager of an organisation who reads the document, which is multiplied by the number of businesses and the reading time to give a familiarisation cost to industry of £102,792.

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[13] PHA total familiarisation cost of £2,574 = 3 hours and 10 minutes (uplifted total familiarisation time) * £20.70 (EHO hourly wage rate including 30% overheads (ASHE))

[14] The equivalent annual cost formula is as follows: EAC=PVC/A, where A = [1-1/(1+r)^t]/r, where PVC is the present value of costs, r is the social discount rate and t is the time period over which the policy is being appraised.

[15] http://www.hm-treasury.gov/uk/data_greenbook_index.htm

[16] Please note these figures have been rounded to the nearest £1.

[17] Source: The Inter Departmental Business Register is accessible via the Office of National Statistics, http://.statistics.gov.uk/idbr/idbr.asp; Figures are the sum of premises listed under SIC 11.07 Manufacture of soft drinks; production of mineral waters and other bottled waters, SIC 17.29 Manufacture of other articles of paper and paperboard n.e.c. SIC 25.92 Manufacture of light metal packaging and SIC 82.92 Packaging activities.

[18] Wage rate obtained from the Annual Survey of Household Earnings (2009) (http://www.statistics.gov.uk/StatBase/Product.asp?lnk=15313). Median hourly wage of 'Production Manager' is used £19.38 plus 30% overheads).

32 The Agency will develop guidance for businesses on the proposed Regulations, which will minimise costs to businesses of reading the Regulations. A brief summary of the guidance is given at paragraph 39 below. The costs to industry are summarised in table 1 below.

33. The familiarisation cost for industry and LA's is summarised in table 1 below, and includes data for the devolved administrations. Table 2 has been broken down to show the number of organisations in the enforcement sector affected and table 3 indicates the number of businesses affected by the proposals.

34. As for enforcement authorities (see above), the one-off costs to industry must also be expressed as equivalent annual costs. The EAC for industry in England is therefore approximately £12,360 and for the UK as a whole is approximately £14,147[19]

[19] Please note these figures have been rounded to the nearest £1.

Table 1

Region	Number of organisations affected		
	Local Authorities	Port Health Authorities	Businesses
England	354	39	2,040
Scotland	32		135
Wales	22	1	100
N.Ireland	26		60
UK	**434**	**40**	**2335**

Table 2

Region	Familiarisation Costs	
	Local Authorities	Businesses
England	£17,227	£102,792
Scotland	£1,325	£6,802
Wales	£997	£5,039
Northern Ireland	£1,076	£3,023
UK	**£20,604**	**£117,656**
Rounded	£21,000	£118,000

Table 3

Summary of firms by size	Micro	Small	Medium	Large	Total
England	1,498	406	109	26	2,040
Wales	73	20	5	1	100
Scotland	99	27	7	2	135
NI	44	12	3	1	60
UK	**1,715**	**465**	**125**	**30**	**2,335**

Notes: Sizes are defined by number of employees per premises as follows: Micro – less than 10 employees; Small – 10-49 employees; Medium – 50-249 employees; Large – more than 250 employees.
Source ONS Inter-Departmental Business Register (2009)

Consultation questions

Stakeholders were asked to comment, with supporting evidence, on whether the assumption that it will take one hour to read and familiarise with the new Regulations is a sensible estimate for enforcement authorities and businesses.

Stakeholders were also asked to comment on any other costs that might be associated with the AIM Regulation or the proposed Regulations and whether they introduce any additional burden.

No comments were received from businesses on the proposed Regulations or on the above specific questions. However there were a number of comments received from enforcement authorities and these are summarised below in the 'consultation comments section below.

Impact on other Government bodies

35. Government departments, such as the Agency, may also be affected as and when they carry out surveys on foods. This may involve having to carry out more research into the migration of substances from food contact materials, including work to establish methodologies for determining such migration and to ensure compliance with the legislation. These are carried out to inform consumers, monitor trends and assess dietary exposure, and to ensure that legislation is effective in protecting consumers from exposure to harmful substances in food packaging.

36. The Agency may also be affected via its enforcement role with regard to the framework Regulation in respect of declarations of compliance, as indicated in Article 16 of that Regulation. Chapter IV, Article 12 and Article 13 of the AIM Regulation require that appropriate documentation be made available to competent authorities on demand to show that their products comply with the legislation.

Administrative Burden Costs

37. The Agency believes that these proposals place no new administrative or additional burdens on businesses or enforcement authorities associated with the proposed statutory instrument that is the specific subject of this impact assessment and that will provide for the enforcement provisions of the AIM Regulation in England. The need for compliance declarations, documentation and labelling are not new burdens, as these are existing requirements under the framework Regulation, Articles 4(5) and 4(6) (labelling of active and intelligent materials and articles), 15(e) and 16.

Guidance on the proposed Regulations

38. The guidance mentioned in paragraph 32 above, is aimed primarily at those businesses that are likely to be affected by the proposed Materials and Articles in Contact with Food (England) Regulations 2010. It is primarily aimed at those businesses that manufacture, use, import or sell active and intelligent materials and articles intended for use in contact with food. The guidance may also be of use to others with an interest in the legislation, such as enforcement authorities. The guidance provides a short summary of the proposed 2010 Regulations and has been produced to explain clearly the legal requirements of the Regulations and should be read in conjunction with the legislation itself.

39. Stakeholders were asked to comment on the content, layout, clarity and whether any more simplified guidance was required for small businesses or for particular sectors and, if so, what form the guidance should take. Although no comments were received from businesses on the guidance, those received from enforcement authorities and trading standards are summarised below in the consultation section of the impact assessment.

Consultation

Within Government

40. During the course of negotiations of the AIM Regulation with the European Commission, officials of the Agency have kept other government departments informed of its progress. These included the Department of Health, the Department for Business, Innovation and Skills, the Foreign and Commonwealth Office, the Cabinet Office, DEFRA and the Office of Fair Trading. To date, no adverse comments have been received from any department.

41. The UK fully supported the Commission's proposal for a specific measure on active and intelligent materials and articles intended to come into contact with food. The final proposal was subsequently adopted by the Standing Committee on the Food Chain and Animal Health.

Public Consultation

42 The Agency has consulted consistently with all of its stakeholders including industry, trade bodies, enforcement bodies, research institutes, consumer groups and any other parties with an interest in policy issues related to food contact materials. Earlier stages in the development of these proposals have been subject to two previous consultations, of which one took place in 2006 and the other in 2008, when these proposals were last amended.

43. The informal consultations carried out in 2006 and 2008 did not raise any pertinent issues about the cost implications in relation to the AIM Regulation from enforcement authorities or businesses. There were however, several comments on points of detail in the 2008 consultation that were noted and, where they did not affect overall UK negotiating lines, were raised in discussions with the Commission and other EU Member States and, in some cases small changes to the text of the AIM Regulation resulted.

44. A third consultation was carried out in October 2009, dealing with a number of specific provisions relating to particular labelling and declaration requirements for goods placed on the market. They specifically concerned the labelling of parts of the packaging that could be wrongly taken by some consumers to be edible, the written declaration of legal compliance to accompany active and intelligent materials and articles prior to retail sale, and the production, to enforcement authorities on request of supporting documentation to substantiate the declaration of compliance. The purpose of this consultation was to ensure that these provisions were in place by 19th December, as discussed in paragraph 10.

Results of the Consultation

45. One hundred and thirty two stakeholders were consulted on these proposals. These included food industry organisations, sector specific organisations, such as manufacturers of food contact materials and more specifically those companies involved in the use and manufacture of active and intelligent materials and articles intended to come into contact with food. Others, including consumer groups, non-government organisations, such as Friends of the Earth and the World Wildlife Fund, enforcement authorities and others with an interest in food contact materials legislation were also consulted. We also consulted the Enterprise Directorate and Forum of Private Businesses.

46. In total 5 responses were received; one from Suffolk Coastal Port Health Authority (PHA), East of England Trading Standards Association (EETSA), the Trading Standards Institute (TSI), the Food and Drink Federation (FDF) and British Glass.

47. The FDF circulated the consultation documents to their members, and commented that their members had no substantive comments on the proposed Regulations. British Glass thanked the Agency for consulting them on the proposed Regulations, and commented that it did not consider the manufacture of glass containers as practiced by British Glass members to fall within the scope of the provisions of these Regulations.

48. The TSI welcomed the opportunity to comment on the proposed Regulations. In relation to the specific questions on familiarisation costs, they supported the Agency's assumption that the proposal did not introduce new or additional costs for businesses and enforcement bodies, other than familiarisation. The TSI also agrees with the Agency's assessment that no new or additional administrative burdens association with the proposal for enforcement bodies. The TSI further agrees with the Agency's assessment that it would take one hour for enforcement authorities to read the proposed Regulations and are not currently aware of any other costs that might be associated with proposed Regulations and believes that there appear to be no new administrative actions. In relation to the guidance, the TSI are satisfied with the content, clarity and layout of the guidance and believe that a more simplified guidance is not necessary. In addition, the TSI is not currently aware of any other impacts under the specific tests from the proposal.

49. The East of England Trading Standards Association (EETSA) agreed with the Agency's assessment that one hour is a sensible estimate for enforcement officers to familiarise themselves with the requirements. They also agreed that there were no new administrative actions which could be identified. However, they felt that more guidance was needed for LA's to identify the different types of AIMS.

50. The EETSA expressed some concerns on the proposed legislation and sought clarification on a number of points. They enquired that as active materials are proposed to be classified as "ingredients" under Directive 2002/13/EC[20], would (a) the requirements of The Food Labelling Regulations 1996 apply (i.e. will the material need to be included in the list of ingredients; (b) what impact will these have on Quantitive Ingredient Declaration (QUID) calculations; and (c) will they be listed by descending order by weight. In response to the first question, after consulting with colleagues dealing with labelling in the Agency and legal, EETSA were informed that, where ingredients have to be listed then any released active substance should appear in the that list and labelled in accordance with the labelling Regulations mentioned above. In response to the second and third questions, EETSA were informed that as QUID laws relate to the quantity of ingredients used at the mixing bowl stage and the said active ingredients would have been absorbed after this stage, the QUID rules would not apply. Subsequently the second question would not be relevant.

[20] Directive 2000/13/EC of the European Parliament and of the Council of 20th March 2000, on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

51. There were several comments from the PHA on the cost element of the impact assessment. They acknowledged that there would be no new or additional costs to enforcement authorities in familiarising themselves with the proposed Regulations. However, they felt that although elements of the legislation are already in force, the PHA understands that no enforcement is undertaken on such products at the point of import. They commented that there was a low knowledge base at the PHA and feel that due to the complex nature of the legislation and the requirements of active and intelligent materials and articles, they would not be able to achieve the one hour proposed to familiarise themselves with the Regulations. The PHA also commented that, they had conducted a three month trial in this particular area and felt that they had insufficient knowledge to contemplate enforcement of any aspects of the legislation. They added that it was difficult to put an actual figure on the amount of time required to obtain understanding of these requirements to enforcement realistic.

52. Furthermore, the PHA feels that the figure given within the evidence base for an officer's time is too low. They currently use an hourly rate of £33.00 for a PHO to calculated statutory costs for carrying out checks. Included in this figure are staff overheads related to training, shift working premiums, but this excludes overheads for business needs such as rent, electric etc. The PHA charge £45.00 for checking organic documents and £50.00 for Common Entry Documents and costs for administration processes to support the presentation of such documents. At present, staff time for examination and sampling consignments are currently charged at £89.50 for those consignments where cost recovery is available and this cost is indicative of the cost to the Suffolk PHA of examining any consignments which they would need to examine and sample to determine compliance under this legislation. As the PHA have only provided unit costs for the examination of each additional document, it is difficult to quantify the volume of additional documentation, which the Port Health Officers would handle as a result of the Regulations.

53. The Agency does not feel that the PHA will incur additional costs for analysing specified food contact materials, as indicated in their comments, as we believe this is within their existing remit and is part of usual operations.

54. The PHA felt that, as there was no cost recovery provisions in the legislation other than for submission of the third part of the formal sample to the Government Chemist when the defendant of formal proceedings requested it; analytical costs, examination costs and documentary checks would all be additional costs that are unacceptable for the enforcement authority. The PHA commented that work had been carried out in this area, which suggests that there is a low level of understanding and compliance with these Regulations for businesses. Suffolk PHA undertook a trial in which 100 consignments of plastic goods intended for food contact were identified and documentation requested. Although only basic checks were undertaken on the documents, none of the consignments had the necessary documentation, which could be classed as covering the required information.

55. The PHA commented that businesses whose goods are within the scope of the AIM Regulation would incur additional costs and would need more time than currently allocated in the evidence base to familiarise themselves with the new requirements. However, the Agency believes that this should not be treated as an additional cost to business as they should be complying with the Regulations.

56. Suffolk PHA feels that there would be additional administrative burdens associated with the proposed Regulations for businesses and enforcement authorities, where enforcement activity is undertaken in the detention of their goods and the presentation of commercial and statutory documentation, as required by the legislation. The PHA also commented that, past experience had shown that they would find a high level of non-compliance amongst declarations of compliance certificates and supporting documentation, resulting in legal action being taken. This in turn, may result in a large administrative burden due to the preparation of case files, and the engagement with legal representatives. However, they were unable to neither quantify nor provide a breakdown of costs, as they rarely have to resort to legal proceedings in their line of work. The PHA added that the majority of their legislation allows them to refuse importation through the service of legal notices on non-compliant consignments either due to documentary errors or unsatisfactory analytical results.

57. Given that there were no comments from businesses on the proposed Regulations, and the views expressed above are from just one PHA, it would be difficult to estimate the level of any additional or new administrative burden for businesses, other than those outlined by the PHA. Other the comments already provided by the PHA they were unable to comment further on the administrative costs to businesses. However, the Agency will look into this matter further to see if there is more general support for the PHA's concerns.

58. The PHA sought clarification on two drafting points in the proposed Regulations. They felt that there were some differences between the enforcement provisions in different parts of the Regulations. In particular, Part 4 which applies to RCF, prevents a person from importing any such film which fails to comply (regulation 10(6)(b) with paragraph (8)), which covers the written declaration. The PHA assumes that they would be able to serve a notice under regulation 32 of the Official Feed and Food Controls (England) Regulations 2009 ("the OFFC Regulations")(although they are seeking further clarification on this in their second question) where there is paperwork that demonstrates non-compliance for such products. This provision they felt, is not available for products covered by other parts of the Regulations where non-compliant paperwork appears to be an offence for which the PHA would have to resort to legal action (i.e. prosecution) for a resolution. The PHA were unclear on what would happen to such a consignment whilst the legal proceedings were taking place and they assume that the consignment would be permitted entry and any legal action would take its natural course.

59. The PHA also sought clarification as to how they would reject any non-compliant consignments at the point of importation, if for example, for those products found to exceed migration limits for their product type. They are aware that the legislation on food contact materials is included under the definition of relevant food law for the purposes of the OFFC Regulations. The PHA wanted to know whether the group of products in the proposed Regulations fall within the definition of feed and food under regulation 32 of these Regulations, which would allow them to serve legal notices requiring detention, re-dispatch or destruction of consignments.

60. In response to the PHA on the first drafting point the Agency's was that the way in which enforcement measures are expressed in Part 4 of the SI is different from the rest of the Regulations because Part 4 is concerned with implementing a Directive, and the rest of the SI deals with enforcing three European Regulations; thus, Part 4 of the Regulations is drafted in terms of prohibition relating to "sell, import or use", (this formulation has historically been used for the Directive on food contact plastics); whereas the EU Regulations are all drafted in terms of "placing on the market" so it is that which is enforced by way of an offence provisions in the SI. There is thus a difference in terminology deriving from the underlying EU legislation, but no differences in substance.

61. In relation to how the PHA deals with non-compliant materials and articles, it is the requirement of regulation 10(8) that RCF should be accompanied by a declaration of compliance at the pre-retail stages; under regulation 10(6)(b), it is prohibited to import a material that is in breach of 10(8), and in breach of the prohibition is an offence under regulation 13(1)(a). It is therefore an offence to import RCF without the relevant documentation, just as it is for the other types of food contact materials and articles for which this SI provides the enforcement mechanism.

62. In response to the point on whether the PHA can resort to serving a notice under regulation 32 of the OFFC Regulations with respect to non-compliant RCF; the Agency's view is that, the import provisions of the domestic OFFC Regulations[21] are based on and draw their legality from Chapter V of the EU OFFC Regulation 882/2004, and these apply explicitly to feed and food. There is no mention of food contact materials. Accordingly there is no legal basis on which to turn away non-compliant food contact materials from outside the EU at point of import. This is an issue that affects the EU at large, and the Agency is currently considering the appropriate course to take for the future.

63. All respondents were thanked for taking part in the consultation, and where required appropriate responses were sent to the PHA and EETSA.

[21] SI No. 2009/3255

Enforcement

64. Enforcement of the proposed Regulations is primarily the responsibility of the LAs and PHAs as defined by the Food Safety Act 1990 and designated in our Regulations. While the making of legislation in England is the function of central government, the enforcement of legislation in England is primarily (but not solely) the responsibility of the 354 LA's and 39 PHAs in England. In relation to local authorities, there is no clear distinction made on the face of the Regulations between county councils, district councils and unitary authorities. However, in non-unitary council areas in England, the food standards work is carried out by the county council and food hygiene work by district councils. In areas under unitary local government, local authorities do both.

Simplification

65. The opportunity is being taken to maintain a simplified single set of Regulations that avoid numerous amendments. An earlier simplification of the regulation of food contact materials legislation was carried out in a two stage exercise in February 2006 and March 2006. Since then we have continued to propose simplified single-set of Regulations to minimise the burden on industry and enforcement authorities. This will help those who need to refer to the Regulations.

Sanctions

66. The criminal sanctions in the current Materials and Articles in Contact with Food (England) Regulations 2007, as amended, would apply in cases of prosecution against those in breach of the new Regulations. A person found guilty of an offence under these and other Regulations dealing with materials and articles in contact with food is liable on conviction on indictment to a fine or imprisonment for a term not exceeding two years or both; on summary conviction to a fine not exceeding the statutory maximum or to a term of imprisonment not exceeding 6 months or to both.

Risk assessment

67. The European Food Safety Authority (EFSA) is responsible for carrying out risk assessments and gives its opinions on substances used in the manufacture of food contact materials based on risk assessment dossiers submitted by industry seeking approval for use of a particular substance. UK experts sit on the EFSA Panels that carry out the detailed risk assessments. The resulting EFSA opinions are given on the basis of protection of public health from the ingestion of harmful levels of substances that may arise from the consumption of food into which the substances may have adventitiously migrated. Any resulting safe consumption limits recommended in EFSA's opinions have margins of safety to ensure that the health of consumers who may eat contaminated foodstuffs would not be affected over their lifetime. The resulting EC proposals on migration limits in food reflect these consumption limits and therefore include these safety margins. The Commission amends these technical limits and refines definitions of categories used for limiting migration as scientific understanding of the substances and their health effects improves. Substances that are deemed to cause unacceptable risk to consumer health, particularly among vulnerable people, are normally prohibited for use unless same means for their use is scientifically established.

68. EFSA is now responsible for carrying the assessment for the Community list of authorised substances that may be used in components of active and intelligent materials and articles. Risk assessment of these substances will be carried out in the manner described above.

69. The risk of not having the Regulations in place would mean that enforcement authorities would not have the necessary powers to enable them to enforce them. Therefore, the obligations to put in place provisions for its enforcement, for offences to be prosecuted and for penalties for those found to be in breach of the AIM Regulations will not be fulfilled. This would lead to the UK Government being cited in infraction proceedings by the Commission and this in turn could result in financial penalties being incurred.

70. Consumer safety may also be compromised and the potential for consumers to be exposed to harmful levels of substances migrating from food contact materials to the food itself.

Competition Assessment

71. We fully considered the questions posed in the Office of Fair Trading competition assessment test[22] and conclude that the proposed Regulations that enforce the AIM Regulation are unlikely to hinder the number or range of businesses or the ability for operators to compete. The proposals are unlikely to significantly affect competition as the impact is likely to be minimal and will apply equally across all food contact industries. The EU legislation is already binding on Member States and the businesses that trade within them. Charities and voluntary organisations are also unlikely to be affected by these proposals.

Small Firms Impact Test

72. We do not consider the impact on small businesses to be significant. This view has been supported by industry and the OFT following earlier consultations on directly applicable European Regulations and during the 2006, 2008 and 2009 consultations on the AIM Regulations. Small and Medium sized businesses were encouraged to respond to issues which they feel may have an impact. To date, no comments have been received from this sector.

Sustainable Development

73. Impacts under the three pillars of sustainable development (environmental, economic and social) have been, and continue to be considered in the preparation of this impact assessment. Option 2 is relatively more sustainable and allows for businesses using intelligent packaging systems which will increase shelf life of foods and indicate spoilage of the food in the packaging, without any adverse impact on consumers. Allowing firms to use the technology has the potential to significantly impact on the amount of packaged food discarded by retailers and consumers and more accurately indicate when foodstuffs have actually spoiled. Since less food will be wasted, less will go to landfill therefore, there will be less greenhouse gas emissions and the positive effect being less energy being wasted that was used in the production of the food.

Race/Gender/Disability Issues

74. The Agency believes that the proposal will have no impact on race, gender or disability equality issues.

75. Stakeholders were asked to comment on whether they were aware of any other impacts under the specific impact tests from the proposed Regulations. The TSI commented that they are not currently aware of any other impacts under the specific tests from the proposals discussed here.

[22] http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft876.pdf

Annex 1: Post Implementation Review (PIR) Plan

Basis of the review: To review progress on how the new requirements of the European legislation are being met by business and enforced by authorities one year after implementation
Review objective: To check that Regulations are operating as expected, thus providing appropriate level of protection for consumers. To check that they are being reasonably achieved by industry.
Review approach and rationale: 1). Monitoring non-compliances through the RASFF system. 2). Feedback from industry and enforcement authorities.
Baseline: Number of non-compliant products reported through the RASFF system currently nil
Success criteria: There continue to be no incidents reported through the RASFF system. Fewer products will be rejected and removed from the supply chain if they have the relevant documentation to substantiate the compliance levels, leading to a reduction in wastage.
Monitoring information arrangements: 1). The Agency will work with enforcement authorities where problems or suspected infringements of the Regulations arise. 2). Essentially it would be up to manufacturers of such products to demonstrate compliance with the Regulations, the effectiveness of which will be monitored via feedback from stakeholders as part of the ongoing policy process.
Reasons for not planning a PIR: [If there is no plan to do a PIR please provide reasons here]